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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,564	08/28/2006	Peter Richardson	13425-170US1	4551

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EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
06/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,564	RICHARDSON, PETER	
	Examiner	Art Unit	
	Lawrence E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 28, 2011 (RCE/amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14,16,17,19-26,29-31 and 51-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14,16,17,19-26,29-31 and 51-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/28/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims **1-10, 15, 18 and 32-46** were previously cancelled, claims **27, 28 and 47-50** have been newly cancelled, claims **11, 19 and 21** have been newly amended, the disclosure has not been amended further, and new claims **53-65** have been added as per the Request for Continued Examination (RCE) and amendment filed February 28, 2011. One additional or supplemental Information Disclosure Statements (IDSs) filed February 28, 2011 has been received, annotated, and made of record. Applicant has also filed a 1.132 declaration in the name of applicant Mssr. Richardson dated February 28, 2011, but said declaration has not yet been submitted with applicant's signature affixed thereto. For this reason the declaration has not been considered.

Claims **11-14, 16, 17, 19-26, 29-31 and 51-65** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **13, 16, 31, 51, 52, 55, 57, 59 and 61** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims **51 and 52** are improperly dependent because both claims depend from now cancelled claim 49.

Applicant's arguments with respect to claims **11-14, 16, 17, 19-31 and 47-52** have been considered but are deemed to be moot in view of the new grounds of rejection.

In claim **13** the term "hyperalgesia is neuropathic pain" is technically erroneous. Did applicant intend the term to read
-- hyperalgesia is caused by a neuropathy --? See also claim **55** wherein the same error reoccurs.

Applicant's arguments with respect to claims **11-14, 16, 17, 19-31 and 47-52** have been considered but are deemed to be moot in view of the new grounds of rejection.

In claim **16** the term "hyperalgesia is inflammatory pain" is technically erroneous. Did applicant intend the term to read
-- hyperalgesia which presents as inflammation accompanied by pain --? See also claim **57** wherein the same error reoccurs.

Applicant's arguments with respect to claims **11-14, 16, 17, 19-31 and 47-52** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claim **31** is improperly dependent for failure to further limit the subject matter of claim **11**.

Applicant's arguments with respect to claims **11-14, 16, 17, 19-31 and 47-52** have been considered but are deemed to be moot in view of the new grounds of rejection.

In claim **59** at line 4, the term "animals" is improperly dependent from claim **53** because the term "animals" has a scope in excess of the scope of the term "human" in claim **53**: e.g. claim **59** fails to further limit the scope of amended claim **53**. See also claim **61** wherein the term "animal" at line 3 causes this claim to have the same problem.

Applicant's arguments with respect to claims **11-14, 16, 17, 19-31 and 47-52** have been considered but are deemed to be moot in view of the new grounds of rejection.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **11-14, 16, 17, 19-26, 29-31 and 51-65** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-16*** of U. S. Patent No. **7,759,321** (PTO-892 ref. **AA**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment both appear to include or imply the treatment of pain and the alleged active ingredients (2-alkoxyadenosines and their 3'-deoxy analogues) are directed to substantially overlapping subject matter.

Applicant's arguments filed February 28, 2011 have been fully considered but they are not persuasive.

Applicant has again acknowledged the instant rejection but has not yet supplied the requested Terminal Disclaimer. Therefore, the instant rejection has been maintained.

Claims **11-14, 16, 17, 19-26, 29-31 and 51-65** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-14*** of U. S. Patent No. **7,790,698** (PTO-892 ref. **AB**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment both appear to include or imply the treatment of pain and the alleged active ingredients (2-alkoxyadenosines) are directed to substantially overlapping subject matter.

Applicant's arguments filed February 28, 2011 have been fully considered but they are not persuasive.

Applicant has again acknowledged the instant rejection but has not yet supplied the requested Terminal Disclaimer. Therefore, the instant rejection has been maintained.

Claims **11-14, 16, 17, 19-26, 29-31 and 51-65** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***32-42*** of pending Application No. **12/859,932**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment limitations both

appear to include or imply the treatment of pain and the alleged active ingredients (2-alkoxyadenosine) are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **11-14, 16, 17, 19-31 and 47-52** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims **11-14, 16, 17, 19-26, 29-31 and 51-65** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1, 3 and 5-20*** of copending Application No. **12/875,035**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment both appear to include or imply the treatment of pain and the alleged active ingredients (2-alkoxyadenosines) are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **11-14, 16, 17, 19-31 and 47-52** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims **11-14, 16, 17, 19-26, 29-31 and 51-65** of this application conflict with claims ***32-42*** of copending Application No. **12/859,932**, and claims ***1, 3 and 5-20*** of copending Application No. **12/875,035**. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **11-14, 16, 17, 19-26, 29-31 and 51-65** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Bartlett et al.** (PTO-1449 ref. **AN**) in view of **Herrick-Davis et al.** (PTO-892 ref. **T**).

The instant claims are directed to a method of treating pain in human hosts in need thereof by the administration of an effective dosage of 2-methoxyadenosine.

Bartlett et al. discloses that spongosine (compound "**18**" is so defined at page 948, column 2, second full paragraph) is further defined as an effective agent to treat inflammation at page 950, column 1, fourth full paragraph, wherein said inflammation has been caused by contact of a test host with carrageenan. Because inflammation is defined to include "redness," "heat," "swelling," "pain," and "loss of function" (Taber's Cyclopedic Medical Dictionary, 19th Ed., 2001, at page 1092, column 1; cited as **Venes et al. (II)**; see PTO-892 ref. **X**), and in view of the effectiveness of the administration of spongosine to treat inflammation according to **Bartlett et al.**, examiner has concluded that spongosine is inherently effective in the treatment of all of the hallmarks of inflammation, including pain.

The **Bartlett et al.** reference did not specifically disclose the testing of spongosine to determine its analgesic activity.

Herrick-Davis et al. discloses that a variety of adenosine analogues that are also known in the art to be adenosine receptor agonists have been found to be analgesic agents with efficacy comparable to morphine. One of the compounds tested, 2-chloroadenosine (CADO), is a close structural relative to spongosine.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to conclude that compounds very closely analogous to CADO disclosed to be a potent analgesic by **Herrick-Davis et al.** to be consistent with an analgesic effect of spongosine as disclosed by **Bartlett et al.** in the treatment of an inflammatory response.

One having ordinary skill in the art would have been motivated to combine these references because both references are directed to disclosures of the analgesic effects observed

following the administration of 2-substituted analogues of adenosine, including one compound (spongosine) defined herein as an active ingredient effective in the treatment of pain and/or inflammation.

Therefore, the instant claimed methods of administration of 2-methoxyadenosine (aka spongosine) to treat pain and/or inflammation would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

Applicant's arguments filed February 28, 2011 have been fully considered but they are not persuasive.

Applicant has argued beginning at page 10 of the instant response that the **Bartlett et al.** reference teaches away from the above rejection, and even when combined with the **Herrick-Davis et al.** reference, does not provide a proper basis for a finding of obviousness. Examiner respectfully disagrees, noting that the disclosure in **Bartlett et al.** at page 950, column 1, second, third, and fourth full paragraphs, has not been accurately represented in applicant's arguments. In particular the data provide in the third and fourth paragraphs makes plain that one of ordinary skill has been taught that to vary the dosages of compounds **16-18** is to vary the observed pharmacological results, that depression of blood pressure and heart rate occurs at a substantially greater dosage level than the anti-inflammatory effect, and that these effects vary within the group of compounds **16-18**. Applicant's arguments appear to be selective quoting data from **Bartlett et al.** without being careful to note the variations in dosages depending on the pharmacological effect being observed, the variations in the compound being administered. In particular applicant has not emphasized that the effect of compound **16** is substantially greater on heart rate and blood pressure than that of compound **18**. In addition the fourth paragraph clearly teaches that the anti-inflammatory effects of the compounds discussed vary with both structure and with dosage, a teaching that arguably gives permission to the ordinary practitioner to pursue the full spectrum of pharmacological effects by the process of routine experimentation, including the effects of variations in dosage of compound **18** on its anti-inflammatory/analgesic properties when administered to a host in need thereof.

For the above stated reasons the instant ground of rejection has been found to remain valid and has been repeated herein.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
06/12/2011

/Lawrence E. Crane/

Primary Examiner, Art Unit 1623

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